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REMARKS

In view of the following remarks, the Examiner is requested to allow Claims 1-7, 9-25, 27-34, 36, 37 and 55, the only claims pending and under examination in this application.

Claim 26 has been canceled without prejudice. Claim 20 has been amended to incorporate the element of Claim 26. Additionally, Claim 20 has been amended to indicate that the quasi-steady gas flow is substantially free of shockwaves. Support for this amendment may be found throughout the specification and claims as originally filed. Specifically, support may be found at page 14, lines 27-28. Accordingly, no new matter has been added by way of this amendment.

As no new matter has been added by way of these amendments, entry thereof by the Examiner is respectfully requested.

Claim Rejections - 35 U.S.C. § 102

Claims 1-6, 9-12, 14-25, 26, 27, 29-32, 34, 36 and 55 remain rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Bellhouse et al. (USPN 5,630,796).

According to the M.P.E.P., a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. The identical invention must be shown in as complete detail as is contained in the claim. See M.P.E.P. § 2131.

As stated above, Claim 20 has been amended. Claim 20 is directed to a needleless injection device. The needleless injection device includes a driver chamber that is arranged to contain a charge of pressurized gas. Further, the needleless injection device includes a duct section, which includes a tube of substantially constant cross-sectional area, wherein the duct section is connected to the driver chamber so as to receive gas from the driver. Further still, the needleless injection device includes a closure means for preventing the flow of gas from

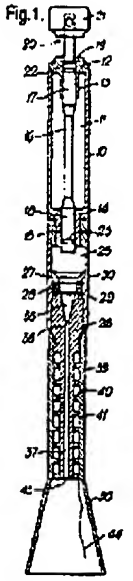
the driver chamber to the duct section until the closure means is opened; and a dose of particles positioned within the device in the region of the closure means.

Additionally, the needleless injection device is constructed and arranged so that upon opening of the closure means, a primary shock wave is produced and travels along the duct section in a downstream direction and a substantially quasi-steady gas flow that is substantially free of shockwaves is established in the duct section upstream of the primary shock wave. In this manner, a dose of particles is substantially wholly entrained in the substantially quasi-steady flow, accelerated and expelled from the device.

Accordingly, elements of Claim 20, as amended, are a duct section which includes a tube of substantially constant cross-sectional area and the establishment of a substantially quasi-steady gas flow that is substantially free of shockwaves. This duct section with the tube that includes a substantially constant cross-sectional area functions, in conjunction with the other elements of the claimed device, to produce a primary shock wave that travels along the duct section in a downstream direction so as to establish a substantially quasi-steady gas flow that is substantially free of shockwaves in the duct section upstream of the primary shock wave. Hence, given the structure of the claimed device, upon operation, a dose of particles will substantially be wholly entrained in the substantially quasi-steady flow without shockwaves, accelerated and expelled from the device.

In the Applicants' response filed December 21, 2006, the Applicants pointed out that Claim 20, as amended, includes a duct section that is of substantially constant cross-sectional area. The Applicants further pointed out that Bellhouse does not teach a duct section that has a substantially constant cross-sectional area. The Office, however, disagrees and asserts that the duct section disclosed in Bellhouse does not change significantly and there is only a minor change in cross sectional area. Thus, the Office concludes that Bellhouse discloses a duct section of "substantially constant cross-sectional area." The Applicants disagree and contend that the position of the Office is contrary to the actual disclosure of Bellhouse.

The device disclosed in Bellhouse is set forth in FIG. 1, below:



The duct section, as disclosed in Bellhouse, includes *convergent part* 35, throat 36 and *divergent part* 37. See, for instance, column 12, lines 44 to 46, below.

> The passageway through the nozzle 26 has an upper convergent (in the downward direction of flow) part 35 leading through a throat 36 to a divergent part 37. The

This design is important to the Bellhouse device because:

> "The *divergence* of the downstream portion significantly affects the velocity of the gas being expanded to pseudo-steady-state, supersonic velocities. Increases in this pseudo-steady-state velocity results in increased particle depth of penetration which is surprising for a phenomenon considered to be predominantly transient. The *divergent* portion also appears to transform the transient flow pattern upon bursting of the membrane into a smooth exit flow from the nozzle, thereby rendering uniform the travel of the particles into their target. In addition the *divergence* of the nozzle causes an even spread of the particles onto the target." See column 5, lines 22 to 33.

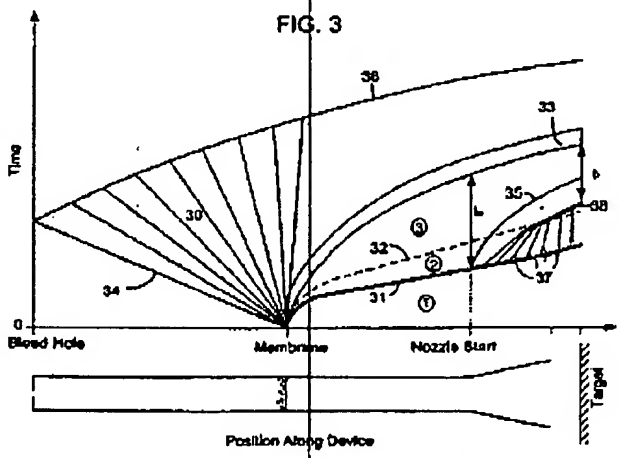
The Applicants contend that in view of the fact that Bellhouse actually discloses a duct section that includes both *convergent* and *divergent* parts, the duct section of Bellhouse

necessarily cannot have a "substantially constant cross-sectional area." The duct section of Bellhouse cannot have a "substantially constant cross-sectional area," because the duct section of Bellhouse is disclosed as having both *convergent* and *divergent* parts, the presence of which is contrary to the meaning of a "substantially constant cross-sectional area," as would readily be understood by one of ordinary skill in the art. Accordingly, for this reason alone this rejection may be withdrawn.

Additionally, the difference in the design and structure of the Applicants' device in comparison to the device disclosed in Bellhouse results in significant differences in the way the two devices function. Specifically, the Bellhouse device is not constructed and arranged so that upon opening of the closure means, a primary shock wave is produced that travels along the duct section in a downstream direction so as to establish a substantially quasi-steady gas flow that is substantially free of shockwaves in the duct section upstream of the primary shock wave.

For instance, a representative embodiment of the quasi-steady gas flow that is substantially free of shockwaves that is established by the Applicants' claimed device is shown in FIG. 3, below.

FIG. 3

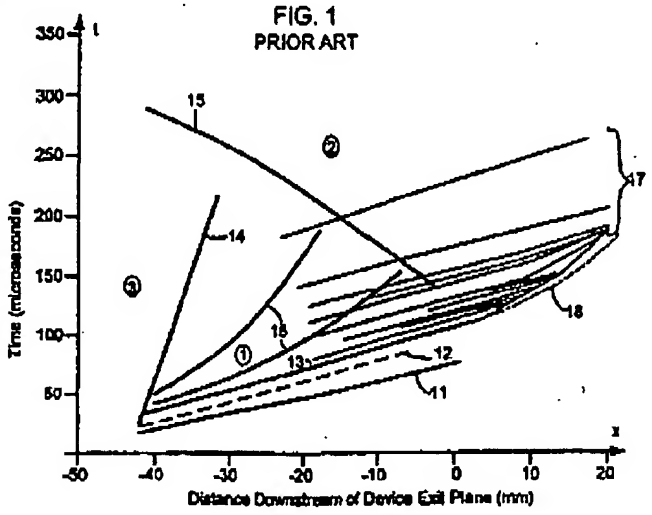


As can be seen with reference to FIG. 3, above, the particles 33 are wholly entrained within the flow, which flow does not contain any shockwaves. Specifically, when the

membrane bursts, the primary shockwave moves forward along the duct of substantially constant diameter and creates a starting process only at the point where the duct section meets the nozzle. At this point, the starting process is characterized by the secondary shockwave (38) and the expansion waves (37). Due to the fact that starting process is initiated downstream of the membrane, the whole process is swept out of the nozzle by the time that the particles (33) arrive. Thus, the particles (33) are wholly entrained within the quasi-steady flow that follows the starting process and the flow does not contain any shockwaves. This is due in part to the structural feature of a substantially constant cross-sectional area duct section.

This is contrasted with the flow that is established in the Bellhouse device, as shown in FIG. 1 of the Applicants' specification, which sets forth the flow of the Bellhouse device of the '796 patent, see below:

FIG. 1
PRIOR ART



The Applicants describe the flow established by the Bellhouse device at page 3, lines 5 to 15, wherein is stated:

"The contact surface 12 is the boundary between the gases that were previously separated by the membrane. It is well acknowledged that the gases do not mix appreciably at this boundary so the effect is one of the driver gas (the gas upstream of the membrane before rupturing) "pushing" the driven gas (the gas downstream of the membrane before rupturing) out of the nozzle like a piston, with the

contact surface 12 being analogous to the face of the piston. The contact surface 12 is closely followed by a secondary shock wave 13. The secondary shock wave 13 is followed by a series of oblique shock fronts 16 within a starting process (region 1 in Figure 1) with large variations in gas density and velocity (and therefore particle velocity). The starting process region 1 is substantially bounded by the shocks 11, 14 and 15; shock front 15 is mentioned further below."

Accordingly, due in part to the fact that the Bellhouse device does not have a duct section with substantially constant cross-sectional area, but rather has a duct section that includes both convergent and divergent sections, the particles to be delivered by the Bellhouse device will get caught up in the starting process and thus be subjected to numerous shockwaves, as shown in FIG. 1 above, which has been experimentally confirmed by the present Applicants. Therefore, because the particles are subjected to numerous shockwaves, the Bellhouse device fails to establish a substantially quasi-steady gas flow that is substantially free of shockwaves. Accordingly, for this reason alone this rejection may be withdrawn.

In view of the above, Claim 20, and the claims dependent thereon, includes structural elements (e.g., a substantially constant duct section), not disclosed in Bellhouse, that function to allow the establishment of a substantially quasi-steady gas flow that is substantially free of shockwaves. The Bellhouse device is deficient in that it discloses a duct section that includes both convergent and divergent parts that cause the particles to be delivered to be caught up in the starting process, and subjected to numerous shockwaves. Therefore, the Applicants contend that Bellhouse does not anticipate the rejected claims because Bellhouse fails to teach all the elements of the claimed invention. Consequently, the Applicants respectfully request that the 35 U.S.C. §102(b) rejection of Claims 1-6, 9-12, 14-25, 26, 27, 29-32, 34, 36 and 55 be withdrawn.

Claim Rejections - 35 U.S.C. § 103

Claims 1-7, 9-18, 20-34, 36 and 55 remain rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Heinzen (WO 97/47730) in view of Bellhouse (USPN 5,899,880).

According to the M.P.E.P. § 706.02 (j), to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The Office asserts that Heinzen discloses a needleless injection device that includes a rupturing membrane closure means 18, diameter driver chamber 13, a duct section 22, dose of particles in region of closure means 14, divergently contoured nozzle 24 through which a flow travels, whereby the device generates an accelerated gas stream upon rupturing the membrane. The Office acknowledges that establishing a quasi-steady flow upstream of a shock wave as well as entraining and accelerating particles in the quasi-steady flow is not taught by Heinzen. The Office, however, concludes that because Heinzen allegedly discloses all the structural elements recited in the Applicants' rejected claims that the operation of the Heinzen device will necessarily result in the establishment of a quasi-steady flow *upstream* of a shock wave as well as the entrainment of the accelerated particles within the quasi-steady flow.

The Applicants respectfully disagree and contend that the reasoning of the Office is erroneous. Simply because one device may have all the structural elements as another device does not necessarily mean that the devices will function in the same manner. Rather, it is how those structural elements are configured and how they interact with one another that determines the functioning of the over all device. Accordingly, the Applicants contend that the Heinzen device does not function in the same manner as the device of claim 20 because the Heinzen device is not configured in the same manner as that of the Applicants' claimed device.

Specifically, as set forth in the Applicants' response filed December 21, 2006, the carrier particles (16) of the Heinzen device are forward (i.e., *downstream*) of the tubing element (13; which the Office equates with the Applicants' claimed driver chamber) and membrane (18). Hence, when the membrane (18) is ruptured the particles (16) will be *downstream* of (e.g., in

front of) the primary shock wave. Because the particles will be in front of the primary shock wave the flow produced will be different from that produced by the device claimed by the Applicants. Therefore, the Heinzen device does not necessarily produce a primary shock wave that travels along the duct section (52) in a downstream direction so as to establish a substantially quasi-steady gas flow that is substantially free of shockwaves in the duct section, *upstream* of the primary shock wave, wherein the particles are wholly entrained within the quasi-steady flow.

Further, to the extent that the Office relies upon Bellhouse to remedy the deficiencies of Heinzen, the device disclosed therein is substantially the same as the device disclosed in Bellhouse '796. Accordingly, the Applicants refer the Office to the above wherein is described that the Bellhouse device is deficient in that it fails to teach or suggest a duct section with substantially constant cross-sectional area and additionally fails to teach or suggest a device that is configured such that upon opening of a closure means, a primary shock wave is established and travels along a duct section in a downstream direction in a manner sufficient to both establish a substantially quasi-steady gas flow without shockwaves, in the duct section upstream of the primary shock wave, and to substantially wholly entrain a dose of particles in the substantially quasi-steady flow. As the Heinzen device is deficient in the same regards, Bellhouse cannot be relied upon to remedy the deficiencies of Heinzen.

Accordingly, the Heinzen and the Bellhouse device are not structured in the same manner as the Applicants' claimed device, and therefore, do not function to allow the claimed entrainment of particles within a quasi-steady flow that is substantially free of shockwaves. Therefore, the Applicants contend that neither Heinzen nor Bellhouse, either alone or in combination, teach or suggest all the elements of the rejected claims. Consequently, a *prima facie* case of obviousness has not been established and the Applicants respectfully request that the 35 U.S.C. §103(a) rejection of Claims 1-7, 9-18, 20-34, 36 and 55 be withdrawn.

Claims 19 and 37 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Heinzen (WO 97/47730) and Bellhouse (USPN 5,899,880) as applied to claims 1 and 36 above, and further in view of Bellhouse (USPN 6,010,478).

Both of Claims 19 and 37 ultimately depend from Claim 20. As set forth above, the device of Claim 20, as amended, includes a substantially constant duct section that functions in conjunction with the other claimed elements of the device to produce a primary shock wave which travels along the duct section in a downstream direction so as to establish a substantially quasi-steady gas flow that is substantially free of shockwaves in the duct section upstream of the primary shock wave.

As set forth above, the combination of Heinzen in view of Bellhouse '880 is deficient in that it fails to teach all the elements of the Applicants' claims. As Bellhouse '478 was cited for its disclosure of scoring a rupturable membrane and selecting different gases to give different velocities, it fails to remedy the deficiencies of Heinzen in combination with Bellhouse '880.

In light of the above, the Applicants contend that a *prima facie* case of obviousness has not been established because the combination of Heinzen in view of Bellhouse '880 and further in view of Bellhouse '478 fails to teach all the elements of the Applicants' claims.

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CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number KEMP-002.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: February 22, 2007

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